DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6443. Dextro-amphetamine sulfate tablets, pentobarbital sodium capsules, and dextro-amphetamine sulfate with amobarbital tablets and capsules. (F.D.C. No. 45323. S. Nos. 29–662/4 R, 53–597 R, 53–600 R.)

QUANTITY: 5 1,000-tablet btls. of dextro-amphetamine sulfate with amobarbital, 3 1,000-tablet btls. and 7 200-tablet bags of dextro-amphetamine sulfate, 1 700-capsule btl. of pentobarbital sodium, and 1 btl., containing 541 capsules of dextro-amphetamine sulfate with amobarbital, at Minneapolis, Minn., in possession of Cedar Drug Co.

SHIPPED: On unknown dates, from outside the State of Minnesota.

LIBELED: 1–4–61, Dist. Minn.

CHARGE: 502(b)—while held for sale, all of the articles failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(1)—the label of the 7-bag lot failed to bear the common or usual name of the drug; 502(f)(1)—the label of the 7-bag lot failed to bear adequate directions for use; and 503(b)(4)—the label of the 7-bag lot failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 2–16–61. Default—destruction.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6444. Food supplements. (F.D.C. No. 44330. S. Nos. 52–117/8 P.)

INFORMATION FILED: 7–20–60, Dist. Minn., against Arthur W. Stemper, t/a A. & N. Stemper Co., and Mrs. Arthur W. Stemper.

ALLEGED VIOLATION: On 7–16–59, in a sales talk at Minneapolis, Minn., the defendants orally represented the articles to persons there present to be an effective treatment for the diseases, symptoms, and conditions set forth below, which act resulted in the articles being misbranded while held for sale after shipment in interstate commerce.

LABEL IN PART: "A Complete Balanced Food Supplement NUTRITION-ALL Proteins—Minerals—Vitamins," and "NUTRITION-ALL High protein."

CHARGE: 502(f)(1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the articles were intended, namely, low and high blood pressure, bad nerves, bursitis, cancer, poor eyesight, rare blood condition, diabetes, and arthritis.

PLEA: Guilty.

DISPOSITION: 11–14–60. Each defendant was fined $100 and placed on probation for 2 years.

6445. Nutrin vitamin and mineral capsules. (F.D.C. No. 44344. S. No. 66–601 P.)

INFORMATION FILED: 7–26–60, W. Dist. Pa., against Chester H. Nairne, t/a Chester H. Nairne Co., Niles, Ohio.

ALLEGED VIOLATION: Between 10–22–59 and 10–29–59, the defendant, in the course of sales talks at Pittsburgh, Pa., made oral representations holding

*See also Nos. 6441, 6443.

out *Nutrin vitamin and mineral capsules* as a treatment and preventive for the diseases, symptoms, and conditions set forth below, which acts resulted in the article being misbranded under 502(f)(1) while held for sale after shipment in interstate commerce.

The information alleged also that the defendant caused a leaflet entitled "Nutrin When Food Alone is not enough Nutrin Capsules" to accompany the article as labeling, which act resulted in the article being misbranded under 502(a) while held for sale after shipment in interstate commerce.

LABEL IN PART: (Btl.) "NUTRIN Multi-Vitamins & Minerals Each capsule contains: Vitamins Vit. A (Fish Liver Oil) 5000 USP units Vit. D (Irradiated Ergosterol) 1000 USP units Vit. B–1 (Thiamine Hydrochloride) 3 mg. Vit. B–2 (Riboflavin) 2.5 mg. Vit. B–12 1.5 mcg. Vit. B–6 (Pyridoxine Hydrochloride) 0.75 mg. Vit. C (Ascorbic Acid) 50 mg. Niacinamide 20 mg. Calcium Pantothenate 5 mg. Folic Acid 0.34 mg. Vit. B (as d-alpha Tocopheryl Acetate) 3 int. units Minerals Calcium 215 mg. Iron 13.4 mg. Phosphorous 166 mg. Potassium 5 mg. Iodine 0.1 mg. Manganese 1.5 mg. Sulphur 10 mg. Cobalt 0.1 mg. Molybdenum 0.4 mg. Zinc 1.4 mg. Copper 1 mg. Magnesium 7.5 mg. 30 Capsules Distributed by CHESTER H. NAIRNE CO. 70 Tenth St. Niles, Ohio."

CHARGE: 502(a)—the leaflet which accompanied the article as labeling contained false and misleading representations that the article was adequate and effective for producing perfect health, active brain, steady nerves, happy disposition, strength, vigor, unlimited energy, sturdy growth, and good bones and teeth; that the article was adequate and effective for the regulation of nervous and muscular activity, coagulation of the blood, proper functioning of the heart, muscles, nerves and body tissues, counteraction of acids, healing of wounds, strengthening of mental power, regulation of all of the nutritive processes, prevention of goiter, purifying the system, and regenerating the body by purifying the blood; and that the food supplies generally available are nutritionally deficient and inferior and lack sufficient amounts of the vitamins and minerals for normal nutrition; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use in the treatment and prevention of the diseases, symptoms, and conditions for which the article was intended, namely, the treatment and prevention of sinusitis, catarrh, neuralgia, bursitis, rheumatism, lumbago, sciatica, gout, arthritis, poor eyesight, premature death, obesity, underweight conditions, nervous breakdown, sleeplessness, tiredness, indigestion, heartburn, irregular bowel movements, nervous strain, poor teeth, half dead feeling, irritability in children, heart disease, diabetes, and colds, for the prevention of tonsillitis, polio, appendicitis, gallstones, and kidney stones, for the treatment of the thyroid and parathyroid glands, and reduced sexual powers, which were the diseases, symptoms, and conditions for which the article was held out to the persons present at the aforesaid sales talks.

PLEA: Nolo contendere.

DISPOSITION: The case was transferred to the United States District Court for the Eastern District of Michigan for the entry of the above-mentioned plea and, on 1–10–61, such court fined the defendant $500.

6446. Figurama device. (F.D.C. No. 42015. S. No. 21–868 P.)

QUANTITY: 12 devices at Kansas City, Mo., in possession of AAA Distributing Corp.